Page 2

Dkt.: P-11209.05

Serial No. 10/743,357

Filing Date: December 22, 2003

Title: EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD

### **Claims**

1. (Canceled)

2. (Amended) A method of priming an integrated extracorporeal blood circuit with prime solution displacing air in the components and lines interconnecting the components of the extracorporeal blood circuit, the integrated extracorporeal blood circuit drawing venous blood from the venous system of a patient through a venous return line and delivering oxygenated blood through an arterial line to the arterial system of the patient during cardiopulmonary bypass surgery adapted to be performed on the patient in the presence of a perfusionist, the priming method comprising:

coupling the venous return line to the arterial line;

supporting the extracorporeal blood circuit in 3-D space so that the components and lines interconnecting the components are disposed between a circuit high elevation and a circuit low elevation;

supporting a prime solution source at a source elevation higher than the circuit low elevation;

delivering prime solution into the integrated extracorporeal blood circuit at the circuit low elevation;

controlling the flow of prime solution from the prime solution source into the extracorporeal blood circuit to upward fill the components and lines of the extracorporeal blood circuit with prime solution;

purging air from the extracorporeal blood circuit as the prime solution rises and fills the extracorporeal blood circuit,

wherein the components of the extracorporeal blood circuit comprise a blood oxygenator, a venous air removal device (VARD), an arterial filter, and a blood pump; and

the supporting step comprises supporting the integrated extracorporeal blood circuit in 3-D space with an oxygenator venous blood inlet and a venous blood outlet of

Page 3

Serial No. 10/743,357 Dkt.: P-11209.05

Filing Date: December 22, 2003

Title: EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD

the blood pump coupled together and with the circuit low elevation, a lower venous blood outlet of the VARD coupled to the venous blood inlet of the blood pump at a VARD outlet elevation above the venous blood inlet of the blood pump, the arterial line coupled to an arterial filter outlet of the arterial filter at an arterial line elevation higher than the VARD [[outlet]] inlet elevation, an arterial filter inlet of the arterial filter coupled to the oxygenated blood outlet of the blood oxygenator and supported at an arterial filter inlet elevation higher than the arterial line elevation, and the venous return line coupled to an upper venous blood inlet of the VARD at a venous return elevation.

### 3. (Original) The priming method of Claim 2, wherein:

the VARD further comprises a VARD housing enclosing a lower VARD chamber and an upper VARD chamber having a VARD purge port,

the controlling step further comprises retrograde filling the lower VARD chamber with prime solution introduced at the circuit low elevation; and

the purging step further comprises purging air from the upper VARD chamber through the VARD purge port.

# 4. (Original) The priming method of Claim 3, wherein:

the arterial filter further comprises an arterial filter housing enclosing a lower arterial filter blood chamber coupled to the arterial filter outlet and an upper arterial filter inlet chamber coupled to the arterial filter inlet and having an arterial filter purge port adapted to be opened and closed;

the controlling step further comprises opening the arterial filter purge port and retrograde filling the lower arterial filter blood chamber with prime solution introduced at the circuit low elevation and rising through the VARD, the venous line and the arterial line coupled to the venous return line,

Page 4

Serial No. 10/743,357 Dkt.: P-11209.05

Filing Date: December 22, 2003

Title: EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD

whereby any air in or entering arterial filter housing accumulates in the upper arterial filter inlet chamber and can be purged through the arterial filter purge port during retrograde filling of the lower arterial filter chamber with prime solution.

5. (Original) The priming method of Claim 4, wherein:

the controlling step further comprises:

closing the arterial filter purge port; and

connecting the upper arterial filter inlet chamber to the upper VARD chamber;

and

the purging step further comprises operating the blood pump to draw air accumulating in the upper arterial filter inlet chamber into the upper VARD chamber to be purged through the VARD purge port.

6. (Original) The priming method of Claim 5, wherein:

the arterial filter inlet of the arterial filter is coupled by an oxygenator outlet line to the oxygenated blood outlet of the blood oxygenator; and

the controlling step further comprises opening the arterial filter purge port and antegrade filling the oxygenator and the oxygenator outlet line with prime solution introduced at the circuit low elevation.

7. (Original) The priming method of Claim 4, wherein:

the arterial filter inlet of the arterial filter is coupled by an oxygenator outlet line to the oxygenated blood outlet of the blood oxygenator; and

the controlling step further comprises opening the arterial filter purge port and antegrade filling the oxygenator and the oxygenator outlet line with prime solution introduced at the circuit low elevation.

8. (Original) The priming method of Claim 3, wherein:

Page 5

Dkt.: P-11209.05

Serial No. 10/743,357

Filing Date: December 22, 2003

Title: EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD

the arterial filter inlet of the arterial filter is coupled by an oxygenator outlet line to the oxygenated blood outlet of the blood oxygenator; and

the controlling step further comprises opening the arterial filter purge port and antegrade filling the oxygenator and the oxygenator outlet line with prime solution introduced at the circuit low elevation.

9. (Original) The priming method of Claim 2, wherein the controlling step comprises in sequence:

interrupting the coupling of the lower venous blood outlet of the VARD with the venous blood inlet of the blood pump;

antegrade filling the blood oxygenator with prime solution;

interrupting the coupling of the oxygenated blood outlet of the oxygenator with the arterial filter inlet of the arterial filter when prime solution rises to the arterial filter inlet;

restoring the coupling of the lower venous blood outlet of the VARD with the venous blood inlet of the blood pump;

retrograde filling the VARD, the venous return line, the arterial line, and the arterial filter with prime solution; and

restoring the coupling of the oxygenated blood outlet of the oxygenator with the arterial filter inlet of the arterial filter when prime solution rises through the arterial filter to the arterial filter inlet.

10. (Original) The priming method of Claim 9, wherein the arterial filter further comprises an arterial filter housing enclosing an upper arterial filter inlet chamber coupled to the arterial filter inlet and a lower arterial blood chamber coupled to the arterial filter outlet, whereby any air in or entering arterial filter housing accumulates in the upper arterial filter inlet chamber during retrograde filling of the arterial filter chambers with prime solution.

Page 6

Serial No. 10/743,357 Dkt.: P-11209.05

Filing Date: December 22, 2003

Title: EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD

11. (Original) The priming method of Claim 9, wherein:

the VARD further comprises a VARD housing enclosing a lower VARD chamber and an upper VARD chamber having a VARD purge port; and

the purging step further comprises purging air from the upper VARD chamber through the VARD purge port while retrograde filling the lower VARD chamber with prime solution introduced at the circuit low elevation.

12. (Original) The priming method of Claim 11, wherein a VARD purge line is coupled to the VARD purge port and the purging step further comprises purging air from the lower and upper VARD chamber through the VARD purge port and VARD purge line while retrograde filling the lower VARD chamber with prime solution introduced at the circuit low elevation.

#### 13. (Original) The priming method of Claim 12, wherein:

the arterial filter further comprises an arterial filter housing enclosing a lower arterial filter blood chamber coupled to the arterial filter outlet and an upper arterial filter inlet chamber coupled to the arterial filter inlet and having an arterial filter purge port adapted to be opened and closed; and

the purging step further comprises opening the arterial filter purge port during retrograde filling of the lower arterial filter blood chamber with prime solution introduced at the circuit low elevation and rising through the VARD, the venous line and the arterial line coupled to the venous return line.

#### 14. (Original) The priming method of Claim 13, wherein:

the arterial filter inlet of the arterial filter is coupled by an oxygenator outlet line to the oxygenated blood outlet of the blood oxygenator; and

Page 7

Serial No. 10/743,357 Dkt.: P-11209.05

Filing Date: December 22, 2003

Title: EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD

the purging step further comprises opening the arterial filter purge port to purge air while antegrade filling the oxygenator and the oxygenator outlet line with prime solution introduced at the circuit low elevation.

15. (Original) The priming method of Claim 14, wherein the purging step further comprises:

closing the arterial filter purge port when the oxygenator outlet line and the arterial filter chambers are filled with prime solution;

connecting the upper arterial filter inlet chamber to the upper VARD chamber; and

operating the blood pump to draw air accumulating in the upper arterial filter inlet chamber into the upper VARD chamber to be purged through the VARD purge port.

16. (Original) The priming method of Claim 9, wherein:

the arterial filter further comprises an arterial filter housing enclosing a lower arterial filter blood chamber coupled to the arterial filter outlet and an upper arterial filter inlet chamber coupled to the arterial filter inlet and having an arterial filter purge port adapted to be opened and closed;

the arterial filter inlet of the arterial filter is coupled by an oxygenator outlet line to the oxygenated blood outlet of the blood oxygenator; and

the purging step further comprises opening the arterial filter purge port to purge air while antegrade filling the oxygenator and the oxygenator outlet line with prime solution introduced at the circuit low elevation.

17. (Original) The priming method of Claim 16, wherein the purging step further comprises:

closing the arterial filter purge port;

Page 8

Dkt.: P-11209.05

Serial No. 10/743.357

Filing Date: December 22, 2003

Title: EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD

connecting the upper arterial filter inlet chamber to the upper VARD chamber; and

operating the blood pump to draw air accumulating in the upper arterial filter inlet chamber into the upper VARD chamber to be purged through the VARD purge port.

18. (Original) The priming method of Claim 2, wherein the controlling step comprises:

antegrade filling the blood oxygenator with prime solution; and retrograde filling the VARD, the venous return line, the arterial line, and the arterial filter with prime solution.

- 19. (Original) The priming method of Claim 18, wherein the arterial filter further comprises an arterial filter housing enclosing an upper arterial filter inlet chamber coupled to the arterial filter inlet and a lower arterial blood chamber coupled to the arterial filter outlet, whereby any air in or entering arterial filter housing accumulates in the upper arterial filter inlet chamber during retrograde filling of the arterial filter chambers with prime solution.
  - 20. (Original) The priming method of Claim 18, wherein:

the VARD further comprises a VARD housing enclosing a lower VARD chamber and an upper VARD chamber having a VARD purge port; and

the purging step further comprises purging air from the upper VARD chamber through the VARD purge port while retrograde filling the lower VARD chamber with prime solution introduced at the circuit low elevation.

21. (Original) The priming method of Claim 20, wherein a VARD purge line is coupled to the VARD purge port and the purging step further comprises purging air from the lower and upper VARD chamber through the VARD purge port and VARD

Page 9

Dkt.: P-11209.05

Serial No. 10/743,357

Filing Date: December 22, 2003

Title: EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD

purge line while retrograde filling the lower VARD chamber with prime solution introduced at the circuit low elevation.

# 22. (Original) The priming method of Claim 21, wherein:

the arterial filter further comprises an arterial filter housing enclosing a lower arterial filter blood chamber coupled to the arterial filter outlet and an upper arterial filter inlet chamber coupled to the arterial filter inlet and having an arterial filter purge port adapted to be opened and closed; and

the purging step further comprises opening the arterial filter purge port during retrograde filling of the lower arterial filter blood chamber with prime solution introduced at the circuit low elevation and rising through the VARD, the venous line and the arterial line coupled to the venous return line.

### 23. (Original) The priming method of Claim 22, wherein:

the arterial filter inlet of the arterial filter is coupled by an oxygenator outlet line to the oxygenated blood outlet of the blood oxygenator; and

the purging step further comprises opening the arterial filter purge port to purge air while antegrade filling the oxygenator and the oxygenator outlet line with prime solution introduced at the circuit low elevation.

24. (Original) The priming method of Claim 23, wherein the purging step further comprises:

closing the arterial filter purge port when the oxygenator outlet line and the arterial filter chambers are filled with prime solution;

connecting the upper arterial filter inlet chamber to the upper VARD chamber; and

operating the blood pump to draw air accumulating in the upper arterial filter inlet chamber into the upper VARD chamber to be purged through the VARD purge port.

Dkt.: P-11209.05

Serial No. 10/743,357

Filing Date: December 22, 2003

Title: EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD

## 25. (Original) The priming method of Claim 18, wherein:

the arterial filter further comprises an arterial filter housing enclosing a lower arterial filter blood chamber coupled to the arterial filter outlet and an upper arterial filter inlet chamber coupled to the arterial filter inlet and having an arterial filter purge port adapted to be opened and closed;

the arterial filter inlet of the arterial filter is coupled by an oxygenator outlet line to the oxygenated blood outlet of the blood oxygenator; and

the purging step further comprises opening the arterial filter purge port to purge air while antegrade filling the oxygenator and the oxygenator outlet line with prime solution introduced at the circuit low elevation.

26. (Original) The priming method of Claim 25, wherein the purging step further comprises:

closing the arterial filter purge port;

connecting the upper arterial filter inlet chamber to the upper VARD chamber; and

operating the blood pump to draw air accumulating in the upper arterial filter inlet chamber into the upper VARD chamber to be purged through the VARD purge port.

- 27. (Canceled)
- 28. (Canceled)
- 29. (Amended) A priming system employed to prime an integrated extracorporeal blood circuit with prime solution displacing air in the components and lines interconnecting the components of the extracorporeal blood circuit, the integrated extracorporeal blood circuit drawing venous blood from the venous system of a patient

Page 11

Serial No. 10/743,357

Filing Date: December 22, 2003

Title: EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD

Dkt.: P-11209.05

through a venous return line and delivering oxygenated blood through an arterial line to the arterial system of the patient during cardiopulmonary bypass surgery adapted to be performed on the patient in the presence of a perfusionist, the priming system comprising:

a pre-bypass loop coupled to venous return line and arterial line connectors effecting coupling the venous return line to the arterial line;

a circuit holder having a vertical mast adapted to extend vertically adjacent to the patient to a hanger and a support arm assembly extending laterally from the vertical mast engaging and supporting the integrated extracorporeal blood circuit in 3-D space so that the components and lines interconnecting the components are disposed between a circuit high elevation and a circuit low elevation, the hanger adapted to support a prime solution source at a source elevation higher than the circuit low elevation;

a prime line adapted to be coupled to the prime solution source and extending to the circuit low elevation;

means for controlling the flow of prime solution from the prime solution source through the prime line into the extracorporeal blood circuit to upward fill the components and lines of the extracorporeal blood circuit with prime solution;

a purge port of the extracorporeal blood circuit adapted to be opened to purge air from the extracorporeal blood circuit as the prime solution fills the extracorporeal blood circuit;

wherein the integrated extracorporeal blood circuit components comprise:

a disposable blood pump having a blood pump inlet and a blood pump outlet and adapted to be operated to draw venous blood into the blood pump inlet and pump the venous blood out of the blood pump outlet;

a disposable venous air removal device (VARD) having an upper venous blood inlet coupled to the venous return line and a lower venous blood outlet coupled to the blood pump inlet, whereby venous blood is drawn through the VARD by operation of the blood pump;

Page 12

Serial No. 10/743,357 Dkt.: P-11209.05

Filing Date: December 22, 2003

Title: EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD

a disposable blood oxygenator having an oxygenator venous blood inlet coupled to the blood pump outlet and an oxygenated blood outlet, the blood oxygenator adapted to be operated to oxygenate venous blood pumped by the blood pump into the oxygenator venous blood inlet;

a disposable arterial filter having an arterial filter inlet coupled to the oxygenated blood outlet of the blood oxygenator and an arterial filter outlet coupled to the arterial line;

a disposable circuit support module coupled to the support arm assembly for supporting the integrated extracorporeal blood circuit in 3-D space with the oxygenator venous blood inlet and the venous blood outlet of the blood pump coupled together at substantially the circuit low elevation, the lower venous blood outlet of the VARD coupled to the venous blood inlet of the blood pump at a VARD outlet elevation above the venous blood inlet of the blood pump, the arterial line coupled to the arterial filter outlet of the arterial filter at an arterial line elevation higher than the VARD [[outlet]] inlet elevation, the arterial filter inlet of the arterial filter coupled to the oxygenated blood outlet of the blood oxygenator and supported at an arterial filter inlet elevation higher than the arterial line elevation, and the venous return line coupled to the upper venous blood inlet of the VARD at a venous return elevation.

30. (Original) The priming system of Claim 29, wherein:

the VARD further comprises a VARD housing enclosing a lower VARD chamber and an upper VARD chamber; and

the purge port comprises a VARD purge port extending through the VARD housing to the upper VARD chamber.

31. (Original) The priming system of Claim 30, wherein the controlling means further comprises means for retrograde filling the blood pump and the lower VARD chamber with prime solution introduced at the circuit low elevation.

Page 13

Dkt.: P-11209.05

Serial No. 10/743,357

Filing Date: December 22, 2003

Title: EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD

32. (Original) The priming system of Claim 31, wherein:

the arterial filter further comprises an arterial filter housing enclosing a lower arterial filter blood chamber coupled to the arterial filter outlet and an upper arterial filter inlet chamber coupled to the arterial filter inlet and having an arterial filter purge port adapted to be opened and closed; and

the controlling means further comprises means for retrograde filling the lower arterial filter blood chamber with prime solution introduced at the circuit low elevation and rising through the VARD, the venous line and the arterial line coupled to the venous return line when the arterial filter purge port is open.

- 33. (Original) The priming system of Claim 32, wherein the controlling means further comprises an arterial filter recirculation line connecting the upper arterial filter inlet chamber to the upper VARD chamber for drawing air accumulating in the upper arterial filter inlet chamber into the upper VARD chamber to be purged through the VARD purge port upon operation of the blood pump.
  - 34. (Original) The priming system of Claim 33, wherein:

the arterial filter inlet of the arterial filter is coupled by an oxygenator outlet line to the oxygenated blood outlet of the blood oxygenator; and

the controlling means further comprises means for antegrade filling the blood oxygenator and oxygenator outlet line with prime solution introduced at the circuit low elevation when the arterial filter purge port is open.

35. (Original) The priming system of Claim 29, wherein:

the arterial filter further comprises an arterial filter housing enclosing a lower arterial filter blood chamber coupled to the arterial filter outlet and an upper arterial filter

Page 14

Serial No. 10/743,357

Filing Date: December 22, 2003

Title: EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD

Dkt.: P-11209.05

inlet chamber coupled to the arterial filter inlet and having an arterial filter purge port adapted to be opened and closed;

the arterial filter inlet of the arterial filter is coupled by an oxygenator outlet line to the oxygenated blood outlet of the blood oxygenator; and

the controlling means further comprises means for antegrade filling the blood oxygenator and oxygenator outlet line with prime solution introduced at the circuit low elevation when the arterial filter purge port is open.

36. (Original) The priming system of Claim 29, wherein the controlling means comprises:

means for interrupting the coupling of the lower venous blood outlet of the VARD with the venous blood inlet of the blood pump

means for antegrade filling the blood oxygenator and oxygenator outlet line with prime solution introduced at the circuit low elevation;

means for interrupting the coupling of the oxygenated blood outlet of the oxygenator with the arterial filter inlet of the arterial filter when prime solution reaches the arterial filter inlet elevation;

means for restoring the coupling of the lower venous blood outlet of the VARD with the venous blood inlet of the blood pump enabling retrograde filling of the VARD, the venous return line, the arterial line, and the arterial filter with prime solution; and

means for restoring the coupling of the oxygenated blood outlet of the oxygenator with the arterial filter inlet of the arterial filter when prime solution reaches the oxygenated inlet blood elevation.

37. (Original) The priming system of Claim 36, wherein the arterial filter further comprises an arterial filter housing enclosing an upper arterial filter inlet chamber coupled to the arterial filter inlet and a lower arterial blood chamber coupled to the arterial filter outlet, whereby any air in or entering arterial filter housing accumulates in

Page 15

Dkt.: P-11209.05

Serial No. 10/743,357

10. 10/743,337

Filing Date: December 22, 2003

Filling Date: December 22, 2003

Title: EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD

the upper arterial filter inlet chamber during retrograde filling of the arterial filter chambers with prime solution.

38. (Original) The priming system of Claim 37, further comprising an arterial filter recirculation line connecting the upper arterial filter inlet chamber to the upper inlet chamber of the VARD, whereby air accumulating in the upper arterial filter inlet chamber is drawn into and purged from the upper VARD chamber upon operation of the blood pump.

39. (Original) The priming system of Claim 29, wherein:

the VARD further comprises a VARD housing enclosing a lower VARD chamber and an upper VARD chamber;

the purge port comprises a VARD purge port extending through the VARD housing through which air within the upper VARD chamber is adapted to be purged; and further comprising:

means for sensing any air accumulating in the upper VARD chamber during retrograde filling of the upper VARD chamber with prime solution and providing a signal for signaling the presence of air in the upper VARD chamber.

40 (Original) The priming system of Claim 29, wherein the arterial filter has an upper arterial filter inlet chamber and a lower arterial blood chamber, whereby any air in the prime solution accumulates during priming in the upper arterial filter inlet chamber.

Page 16

Serial No. 10/743,357 Dkt.: P-11209.05

Filing Date: December 22, 2003

Title: EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD

# 41. (Original) The priming system of Claim 40, wherein:

the arterial filter further comprises an arterial filter purge port through the arterial filter housing to the upper arterial filter blood inlet chamber, and further comprising:

an arterial filter recirculation line extending between the arterial filter purge port and the venous return line coupled to the upper venous blood inlet, whereby air accumulating in the upper arterial filter inlet chamber is drawn by the blood pump into the upper VARD chamber.